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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,836	11/21/2003	Yitzhak Zilberman	A328B-USA	1327

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EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

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05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,836	ZILBERMAN ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26* is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3-14, 16-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Maschino et al. (US 6,600,956).

3. Maschino discloses the invention as claimed including a placement comprising a holder with a hollow cavity (examiner considers Maschino to disclose a substantially hollow cavity as seen in Fig. 1A) adapted for holding an implantable medical device (examiner considers the implantable medical device in this instance to be the sensing/stimulating electrodes 13, 14, and 15), an elastic body with wing portions (elements 24, 26 and side cavity side members) for capturing the neuromuscular tissue, and the structure being formed of biocompatible plastic (e.g. Col. 5, lines 33-34; Col. 4, line 43).

4. It is of note that the newly added claim limitations to Claim 1, "... said implantable device is selected from the group consisting of: microstimulators, microsensors, and microtransponders..." is a mere intended use functional recitation. Examiner considers the system disclosed by Maschino as capable of

accommodating one of a microsensor, microstimulator, or microtransponder as Maschino discloses and meets all structural claimed limitations, and since the size and shape of the implantable medical devices are relative and have not been set forth in the claim. Further Examiner considers the sensing/stimulating conductors 13, 14, and 15 to be microstimulators and microsensors.

5. With regard to claims 3 and 16, Examiner considers the elastic wings as explained above to be the same as a hook portion for trapping the neuromuscular tissue within the cavity as seen in Fig. 1A and Fig. 3.

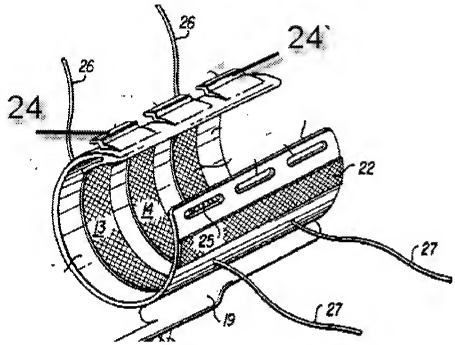
6. Maschino discloses the implantable device is substantially tubular as seen in Fig. 1A, element 13, with the holder being substantially semi-circular in cross section having a first and second end plate enclosing the hollow cavity in-between. Examiner considers the distal ends of the electrode structure to have end plates integrally formed with the hollow cavity holder for securing the electrodes to the holder structure.

7. With regard to claims 7 and 20, Examiner considers the structure as disclosed by Maschino to inherently reduce the flow of eddy currents. Maschino discloses the prevention of current spread which in its broadest reasonable interpretation would also be considered an eddy current because an eddy current runs contrary to a main current).

8. With regard to claims 8-9 and 21-22, Maschino disclose multiple embodiments where the conductive path is either comb shaped (Figs. 4D-4E) or serpentine (Fig. 1A; column 4, lines 32-33; Col. 7, lines 30-32 where the

serpentine conductive path is created by way of the braided or woven conductive strands).

9. With regard to Claim 10, Examiner considers Maschino to disclose two separate sets of wings.



10.

11. Examiner has relabeled in the figure above to better illustrate what is considered the first and second sets of wings. Wing 24 substantially connects the first electrode, 13, to the holder member and the neuromuscular tissue; conversely, wing member 24` substantially connects electrode 15 to the holder member and neuromuscular tissue. This can also be seen in alternate embodiment shown in Fig. 3.

12. Regarding claims 11 and 24, Maschino et al. disclose an implantable device has proximal and distal electrodes (Fig. 3, elements 13 and 14) and a placement structure comprises first and second opposing wings (Fig. 3, elements

34 and 35) and wherein a first electrically conductive path is formed between a proximal portion of a hollow cavity and a first wing (13 and 34) and a second electrically conductive path is formed between a distal portion of a hollow cavity and a

second wing (14 and 35), wherein a proximal electrode of an implantable device is capable of being electrically connected to an inner portion of a first wing because the wing elastically expands and will stretch to accommodate an implantable device and because the size and dimensions of the implantable device have not been set forth and the wing has conductive strips on its inner surface (column 9, lines 3-7) and a distal electrode of an implantable device is capable of being electrically connected to an inner portion of a second wing (column 9, lines 3- 7) when an implantable device is inserted within a holder because the wing elastically expands and will stretch to accommodate an implantable device and because the size and dimensions of the implantable device have not been set forth and the wing has conductive strips on its inner surface.

13. With respect to claims 12 and 25, Maschino et al. disclose a distal portion of a holder includes a boot type structure (Fig. 7A, the structure including elements 99, 104 and 106) having an inner surface capable of holding a distal end of an implantable device because the holder elastically expands and will stretch to accommodate an implantable device and wherein at least a portion of an inner surface of a boot type structure is capable of including electrically conductive

paths for providing electrical connection between a distal electrode of an implantable device and a second wing when an implantable device is inserted within a holder because the wings have conductive strips on the inner surface that share a common electrical lead coupled between the wings.

14. Regarding claim 13, Maschino et al. disclose an implantable device has a plurality of sensor/stimulator portions coupled to a plurality of electrode connectors at the outer surface of the implantable device (Fig. 1A, elements 13-15 and 20), a placement structure additionally comprising: a plurality of electrodes distributed within the wings (elements 13-15); a plurality of electrically conductive portions within a holder (column 7, lines 9-13) and a hollow cavity capable of coupling the electrode connectors of an implantable device to the plurality of electrodes because the hollow cavity has conductive strips exposed on the outer surface connected to a lead that would connect with the electrode connectors of the implantable device; and wherein a structure is suitable for interfacing to the electrodes to selectively sense signals from the neural/muscular tissue .(column 11, lines 17-20).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 2 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maschino as applied above.

18. With regard to claims 2 and 15, Maschino discloses the invention as claimed but fails to teach the apparatus being made of sillastic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Maschino with using sillastic since such a modification would provide the predictable results of a known biocompatible material that would elastically expand and not be rejected by the body. Further it would have been obvious to one having ordinary skill in the art at the time the invention was made to try using sillastic since the selection of sillastic would yield a reasonable expectation of success. Moreover, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability of the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. See MPEP 2144.07

Allowable Subject Matter

19. Claim 26 is allowed.

Response to Arguments

20. Applicant's arguments filed 1/15/2007 have been fully considered but they are not persuasive.

21. Applicant argues that Maschino fails to disclose a hollow cavity. As explained above Examiners considers the body structure to be hollow and adapted for receiving the electrode and the neuromuscular tissue. It is of note that a separate cavity is not needed for receiving the stimulator.

22. In the alternative Applicant has argued that the hollow holder is not preformed prior to implantation. Examiner notes that this is not a ***claimed*** limitation of either claim 1 or 16.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Joseph Stoklosa/
Examiner, Art Unit 3762
5/7/2008

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